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GERSTENZANG, WILLIAM C.			HOLT, ANDRIAE M	
NORRIS MCLAUGHLIN & MARCUS, PA				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,608	Applicant(s) EBLE ET AL.	
	Examiner Andriae M. Holt	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 September 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4 and 6-13 is/are pending in the application.
- 4a) Of the above claim(s) 7-10,14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-4, 6, and 11-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3-4, and 6-13 are pending in the Application. Claim 1 has been amended.

Election/Restrictions

Applicant's election with traverse of Group 1, claims 1-6 and 11-13, in the reply filed on July 6, 2010 and September 16, 2010 is acknowledged. The traversal is on the ground(s) that the current application is a PCT-national phase entry and that the examiner is bound to the determinations of the PCT and therefore should reconsider the restriction requirement in view of the opinion of the international search authority. This is not found persuasive because under PCT Rule 13.2 (i), lack of unity of invention cannot be found in cases claiming product, process of making and process of using, where process of making is "specially adapted" for manufacture of product, even if product may have other uses than claimed. In the instant application, the process of making is not "specially adapted" for manufacture of product and lack of unity of invention is proper. In the process of making claim, independent claim 1, the active substance A) has a solubility of greater than 1% by weight and is dissolved in a low molecular weight organic solvent 1. The active substance A) of the product claim, independent claim 7, is a predominantly amorphous active substance that is crystalline at 50° C. An active substance that has a solubility greater than 1% by weight is not necessarily crystalline at 50° C. The product claim has a dispersing agent C) selected from the group consisting of nonionic, anionic, cationic, and zwitterionic surface-active compounds. The component C) dispersing aid of the process of making claim is an optional component.

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Therefore, the process of making the products as disclosed in claim 1 can be performed without component C), which is a necessary component in the product claim. As such, the process for preparing the product was not "specifically adapted" for the manufacture of the product. In addition, if multiple products are claimed, the first invention of the category mentioned in the claims of the application will be considered as the main invention in the claims, see MPEP 37 CFR 1.475. Groups II and III are drawn to two different product claims, as such, restriction between the product claims is proper. Also, as stated in the restriction requirement, compositions comprising an active substance, a polymer and dispersing agents and processed for their preparation are known in the art as evidenced by the following patents: US 5,780,062, EP 1,344,520, and US 6,458,745. Thus, a feature found in the prior art cannot be considered to be a special technical feature.

The requirement is still deemed proper and is therefore made FINAL.

Claims 7-10 and 14-15 remain withdrawn from further consideration, as being drawn to a non-elected invention. Claims 1, 3-4, 6, and 11-13 will presently be examined to the extent they read on the elected subject matter of record.

Status of the Claims

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections are newly applied. They constitute the complete set of rejections presently being applied to the instant application.

New Rejections Necessitated by Amendment filed September 16, 2010

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-4, 6, and 11-13 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Runge et al. (US 6,458,745) in view of Lott (US 5,664,733).

Applicant's Invention

Applicant claims a process for preparing amorphous active substance formulations comprising steps a)-e). Applicant claims mixing solvent streams of E) and F) in a mixing nozzle, with the two streams being fed continuously and uniformly to the mixing zone of the mixing nozzle. Applicant claims the viscosity of solutions E) and F) is kept below 100 mPas.

**Determination of the scope of the content of the prior art
(MPEP 2141.01)**

Runge et al. teach a solid crop protection composition consisting essentially of a) one or more amorphous crop protection active ingredients which are solid per se and have solubility in water of less than 500 mg/l at 25° C and b) a coating enclosing component (a) (Abstract). Runge et al. teach that to achieve particles as small as possible upon mixing, it is expedient to produce a vigorous turbulence in the mixing chamber by stirring or shaking the active the active ingredient solution and the dispersing solution with mechanical aids or, in particular, by injecting a forced stream of these two components into a mixing chamber (col. 9, lines 55-60). A suspension of the crop protection active ingredient in the solvent of choice in concentration of 0.1 to 50% by weight of stabilizers is introduced into container (1). Container (2) contains the solvent without admixture of the crop protection active ingredient. The active ingredient suspensions and the solvent are fed to the mixing chamber via pumps. It being possible for the mixing ratio to be set by selecting the flow rate of each of the pumps and it is chosen in such a way that an active ingredient concentration of 0.02 to 40% by weight based on the solution is formed in the mixing chamber (col. 9, lines 63-67-col. 10, lines 1-11). Runge et al. teach that before entering the mixing chamber, the solvent is brought to the desired temperature via the heat exchanger. Turbulent mixing causes the active ingredient to dissolve in the temperature range of 20° C to 240° C, and the resulting solution enters the second mixing chamber in which the active ingredient is precipitated in colloid-disperse form by admixing the dispersing solution via pump. The fine active ingredient dispersion leaves via the pressure control valve and enters the

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storage container (col. 10, lines 12-21). Runge et al. teach the solvents can be removed from the colloid-disperse intermediate in a manner known per se, such as freeze drying. The preferred method is spray granulation, in particular spray drying and the twin emulsion method (col. 10, lines 38-46). Runge et al. teach to promote the disintegration of agglomerates upon dispersing the dry powder prior to use, the addition before drying of a spray adjuvant such as lactose or polyvinylpyrrolid-2-one to the colloid-disperse product after the mixing step is advantageous (col. 10, lines 55-59). Runge et al. teach that in a preferred embodiment of the process, the active ingredient solution is prepared in the presence of a stabilizer. Very particularly preferred are ascorbyl palmitate and copolymers of acrylic acid and styrene (col. 10, lines 60-65). Runge et al. teach the preparation of a dry powder in preparation example 1, col. 14, lines 65-67-col. 15, lines 1-41. Chlorpyrifos was stirred into a solution of ascorbyl palmitate in acetone giving a clear solution. This solution was mixed with acetone in the mixing chamber. The chlorpyrifos was precipitated in colloid-disperse form in such a way that, after a residence time of 3.2 seconds, the molecular disperse solution was fed into the mixing chamber (step a). There, the material was mixed with an aqueous solution of gelatin B 100 Bloom, Gelita Sol P and lactose in fully demineralized water (steps b, c, and d). A white, cloudy colloid-disperse chlorpyrifos dispersion was obtained in the receiving vessel. Spray drying of the product from Preparation Example 1 a) gave a free-flowing nanoparticulate dry powder (e).

Runge et al. teach suitable organic solvents which are miscible with water include alcohols, ethers, esters, ketones and acetals of this type. Substances include

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ethanol, isopropanol, and acetone (col. 9, lines 25-34) (solvents). Runge et al. teach materials that are suitable for coating are boundary-or surface acting polymeric colloids or amphiphilic (col. 7, lines 40-43). Runge et al. disclose polymeric colloids include gelatin, dextrin, gum, alginates and starch (col. 7, lines 44-51). Runge et al. teach synthetic anionic, cationic, and neutral polymers include polyvinyl alcohol and polyvinylpyrrolidone (col. 7, line 52-62) (polymer B).

***Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)***

Runge et al. do not specifically disclose that the mixing solvent streams of solutions E) and E) in a mixing nozzle forming a turbulent flow or that the viscosity of solutions E) and F) is kept below 100 mPas. It is for this reason Lott is added as a secondary reference.

Lott teaches an improved fluid mixing nozzle that creates chaotic turbulent flow and induces vortices to form in the flow, thereby, transferring energy and velocity from the flow core to the boundary (col. 1, lines 5-9). Lott teaches an improved fluid mixing nozzle that: accelerates a fluid; provides improved mixing of fluids, including both bulk mixing and molecular dispersion; facilitates the use of shorter diffusers in eductors; permits the use of diffusers having a taper angle up to 35 degrees; creates a chaotic turbulent flow; induces vortices to form in the flow; transfers energy and velocity from the flow core to the boundary layer and, thereby, energizes the boundary layer; improves entrainment in eductors; permits convergence of resulting independent flows at a predetermined point downstream of the nozzle; generates a substantially uniform exit flow profile from a diffuser; and when used in an eductor, obtains a pressure

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recovery of at least 80 percent (col. 2, lines 24-43). Lott teaches that to achieve such improvements, the invention is an improved fluid mixing nozzle in which a first fluid flows therefrom to mix with a second fluid external the nozzle (col. 2, lines 44-48). Lott teaches that functionally applying the fluid mixing nozzle provides a method for vortex induction and for creating chaotic turbulent flow. A method of improved mixing comprises the steps of providing a nozzle, similar to the one described above, that is capable of creating a chaotic turbulent, accelerated flow therefrom. Lott teaches that a first fluid directed through and accelerated by the nozzle contacts and mixes with a second fluid. Lott teaches that when the nozzle is applied to an eductor, the mixing of the accelerated first fluid with the second fluid takes place immediately downstream of the nozzle in the mixing area. The second fluid may be stationary relative to the accelerated first fluid or may flow into the contact with the first fluid by injection or other means. Lott teaches that the mixed fluid may flow into a containment structure such as a diffuser or an open container (col. 5, lines 13-31).

Lott teaches that experiments to evaluate the performance of the nozzle reveal that in use the nozzle emits large scale vortices that transfer energy and velocity from the flow core to the boundary layer. The resulting flow pattern from the nozzle includes a vortex from each protrusion. The nozzle, additionally, provides a chaotic turbulent flow which permits the use of shorter diffusers in an eductor. Lott teaches the chaotic turbulent flow and the vortices provide for enhanced mixing (col. 5, lines 32-40).

***Finding of prima facie obviousness
Rationale and Motivation (MPEP 2142-2143)***

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It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Runge et al. and Lott and mix the solvent streams of solutions E) and F) in a mixing nozzle forming a turbulent flow. Runge et al. teach that to achieve particles as small as possible upon mixing, it is expedient to produce a vigorous turbulence in the mixing chamber. Runge et al. teach that the turbulent mixing of the molecular-disperse solution of the crop protection active ingredient with the liquid formulation of the coating material converts the former into a colloid-stable dispersion of coated particles of the essentially amorphous crop protection active ingredient. One skilled in the art at the time the invention was made would have been motivated to use the mixing nozzle as taught by Lott as the mixing chamber to form the coated particles of the essentially amorphous crop protection active ingredient because the nozzle creates a chaotic turbulent flow. Therefore, it would have been obvious to the skilled artisan that the chaotic turbulent flow and the vortices produced by the mixing nozzles would provide for enhanced mixing and would produce the turbulent mixing of the molecular-disperse solution of the crop protection active ingredient with the liquid formulation of the coating material to convert the former into a colloid-stable dispersion of coated particles of the essentially amorphous crop protection active ingredient.

It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Runge et al. and Lott and keep the viscosity of the use solutions E) and F) below 100 mPas as a matter of routine experimentation and optimization. One skilled in the art at the time the invention was made would have been motivated to keep the viscosity below 100 mPas to optimize the rate of flow of the

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solutions when mixing the solutions streams, particularly if using equipment that has mixing nozzles to ensure the solutions will flow through the nozzles. The adjustment of particular conventional working conditions (e.g., determining viscosity) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Accordingly, this type of modification would have been well within the purview of the skilled artisan and no more than an effort to optimize results.

Therefore, the claimed invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

Response to Arguments

Applicant's arguments filed July 6, 2010 and September 16, 2010 have been fully considered but they are not persuasive. Applicant argues that Runge fails to teach the use of a mixing nozzle and the use of the nozzle to form a turbulent flow. In response to Applicant's arguments, a new rejection necessitated by the amendment to the claims, that the mixing of solvent streams of solutions E) and F) in a mixing nozzle is no longer optional, is set forth in the rejection above. It would have been obvious to one of ordinary skill in the art at the time of invention to combine the teachings of Runge et al. and Lott and mix the solvent streams of solutions e) and f) in a mixing nozzle forming a turbulent flow. Runge et al. teach that to achieve particles as small as possible upon mixing, it is expedient to produce a vigorous turbulence in the mixing chamber. Runge et al. teach that the turbulent mixing of the molecular-disperse solution of the crop

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protection active ingredient with the liquid formulation of the coating material converts the former into a colloid-stable dispersion of coated particles of the essentially amorphous crop protection active ingredient. One skilled in the art at the time the invention was made would have been motivated to use the mixing nozzle as taught by Lott as the mixing chamber to form the coated particles of the essentially amorphous crop protection active ingredient because the nozzle creates a chaotic turbulent flow. Therefore, it would have been obvious to the skilled artisan that the chaotic turbulent flow and the vortices produced by the mixing nozzles would provide for enhanced mixing and would produce the turbulent mixing of the molecular-disperse solution of the crop protection active ingredient with the liquid formulation of the coating material to convert the former into a colloid-stable dispersion of coated particles of the essentially amorphous crop protection active ingredient.

None of the claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDRIAE M. HOLT whose telephone number is (571)272-9328. The examiner can normally be reached on 7:00 am-4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richter Johann can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Andriae M. Holt
Patent Examiner
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/John Pak/
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